DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#19

DEC 28 1993

Re: Sporanox®
Docket No. 92E-0472

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,267,179, filed by Janssen Pharmaceutica N.V., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Sporanox®, the human drug product claimed by the patent.

The total length of the review period for Sporanox® is 2,990 days. Of this time, 2,155 days occurred during the testing phase and 835 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 7, 1984.

   Applicant claims June 7, 1984 as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 7, 1984, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: May 31, 1990.

   The applicant claims May 30, 1990, as the date the New Drug Application (NDA 20-083) was initially submitted. However, FDA records indicate that NDA 20-083 was initially submitted on May 31, 1990.

3. The date the application was approved: September 11, 1992.

FDA has verified the applicant's claim that NDA 20-083 was approved on September 11, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Charles J. Metz, Esq.
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